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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/985,974	11/07/2001	Jorge D. Brioni	6753.US.02	4598

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EXAMINER

WANG, SHENGJUN

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 10/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/985,974

Applicant(s)

BRIONI ET AL.

Examiner

Shengjun Wang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-6,8,9,11,12,14-23,25-27 and 29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-6,8,9,11,12,14-23,25-27 and 29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Receipt of applicants' amendments and remarks submitted August 16, 2004 is acknowledged.

Claim Rejections 35 U.S.C. 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 2, 4-6, 8, 9, 11, 12, 14-23, 25-27, 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fliri et al. (WO 0099/09025) and Glass et al (IDS) in view of Fliri et al. (US 5,883,094), and Faraci et al. (US 5,889,010).

3. Fliri et al (WO 99/09025) teaches indole derivatives, including CP-266,269, as dopamine D4 agonist. See, particularly, page 1, page 4, and pages 13-14. Glass et al. teaches that N-[[4-(2-cyanophenyl)-1-piperazinyl]methyl]-3-methyl benzamide is a known selective D4 receptor agonist, see particularly, table 1, compound 6. Fliri et al. further teaches method of using dopamine D4 receptor selective compounds for treating various dopamine related disorders. See, particularly, page 4, line 30 to page 5, line 10.

4. The primary references do not teach expressly the employment of dopamine D4 agonist for treating sexual dysfunction.

5. However, Fliri et al. (US 5,883,094) and Faraci et al. teaches that it is known in the art that dopamine receptors are important for many functions in the animal body, such function

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including sexual behavior, and suggest that D4 dopamine receptor selective compounds may exert a wide range of therapeutical effect. See, particularly, column 1 in both references. Fliri et al. and Faraci et al. further teach that compounds having selective D4 dopaminergic activity are known to be useful for treating sexual dysfunction. See, particularly, column 3-5, 10-11 and the claims in Fliri et al. and column 6, line 62 to column 9, line 60, column 20, line 35 to column 22, line 55 in Faraci et al.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ D4 receptor agonists, such as those disclosed by Fliri et al.(WO 99/09025) and Glass et al. for treating sexual dysfunctions

A person of ordinary skill in the art would have been motivated to employ D4 receptor agonists, such as those disclosed by Fliri et al.(WO 99/09025) and Glass et al. for treating sexual dysfunctions because dopamine receptors are generally known to be related to sexual behavior, and, compounds having selective D4 dopaminergic activity are particularly known to be useful for treating sexual dysfunction.

Response to the Arguments

Applicants' amendments and remarks submitted August 16, 2004 have been fully considered, but are not persuasive.

In traversing the rejections under 35 U.S.C. 103, applicants assert that Fliri et al (US 5,883,094) and Faraci et al. do not teach or suggest the employment of dopamine agonist for treating sexual dysfunction since the two references teach the employment of dopaminergic compounds for treating sexual dysfunction, wherein the dopaminergic compounds including both dopamine agonist and antagonist (compounds increase or decrease in dopamine mediated

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neurotransmission). Applicants' assertion is in error. If a genus consisting of two subgenus is taught to be useful for certain utility, employment of any of the subgenus for the utility would have been fairly suggested. In the instant situation wherein dopaminergic compounds were known to be useful for treating sexual dysfunctions, the employment of dopamine agonists for treating sexual dysfunction would have been fairly suggested.

6. Applicants further argue that the claimed inventions have unexpected benefits.

Applicants' arguments, and the data presented in the application have been fully considered, but are not persuasive. Particularly, the compared subject matter, apomorphine, is not considered as the closest prior art. The closest prior art herein would be the selective D4 dopaminergic compounds disclosed by Fliri et al. (US 5,883,094), and Faraci et al. (US 5,889,010), which are known for treating sexual dysfunction disorders. Further, the results are not commensurate in the scope of most of the claims.

Regarding the establishment of unexpected results, a few notable principles are well settled. It is applicant's burden to explain any proffered data and establish how any results therein should be taken to be unexpected and significant. See MPEP 716.02 (b). The claims must be commensurate in the scope with any evidence of unexpected results. See MPEP 716.02 (d). Further, it must compare the claimed subject matter with the closest prior art in order to be effective to rebut a prima facie case of obviousness. See, MPEP 716.02 (e).

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SHENGJUN WANG
PRIMARY EXAMINER
Shengjun Wang
Primary Examiner
Art Unit 1617